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10/552,697	07/27/2006	Pentti Korhonen	43289-223931	2415
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VENABLE LLP			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/552,697	Applicant(s) KORHONEN, PENTTI	
	Examiner Brian T. Gedeon	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This action is in response to the Amendment after Non-Final filed 1 June 2007.

Claim Rejections - 35 USC § 112

In the previous Office action, claims 37, 50, 55, and 60 were rejected under 35 U.S.C. 112 as being indefinite. In view of the amendment, the 112 rejections are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 34, 38-43, 49, 50-52, and 56-65 rejected under 35 U.S.C. 102(a) as being anticipated by MacAdam et al. (WO 02/058550).

In regard to claims 34, 43, 52, 61, and 65, MacAdam et al. disclose a method and system for sensing an ECG signal, detecting at least one QRS-T wave segment, processing said wave segment to extract the p-wave signal, p 5 lines 19-25 and p 8 lines 1-9. The p-wave, as taught by MacAdam, can be a valuable tool used by clinicians to diagnose certain conditions of the heart, and is easily elicited by a 12-lead ECG system. MacAdam et al. also teach that in some cases due to premature atrial

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contractions the p-wave can be obscured by the t-wave of the ECG, which presents a physiologically compromised state for the heart, as well as makes the p-wave useless to physicians in diagnosing conditions of the heart, p 3 lines 3-17 and p 4 lines 11-14. The Examiner interprets this as suggesting that it is necessary for the p-wave to be acquired an examined without any atrial extrasystoles or premature contractions, and therefore MacAdam et al. provide the necessary teaching for the exclusion of atrial extrasystoles in the acquired ECG signal. Cardiac analysis is performed by comparing a p-wave identified from the ECG signal to a p-wave with a previously captured reference template, p 8 lines 1-9 and p 13 lines 4-6, which leads to the discovery of the focal origin of the wave, p 6 lines 19-23. The morphology of the p-wave is the essential element in the p-wave reference template matching, wherein the morphology of the p-wave is considered by the Examiner to be indicative of a "dynamic change", since the morphology of the acquired signals can be different in each acquired sample because of different points of focal origin. Analysis is performed in a defined time period, wherein the a user define the time period by placing marks signaling the beginning and ending points of the acquired signal, p 7 lines 19-20.

In regard to claims 38, 39, 56, and 57, the system and method of MacAdam et al. acquires data from multiple leads in order to form a template for reference template matching.

In regard to claims 41, 42, 60, and 62, signals are sensed from multiple ECG leads and averaged together to form the reference template signal, p 5 lines 15-18.

In regard to claims 49 and 62, MacAdam et al. teach that is well known in the art to use a 12 lead ECG in an attempt to correlate changes in P wave morphology, p 5 lines 8-10.

In regard to claims 50 and 63, figure 4 of MacAdam et al. show that the ECG signals can be stored in an storage unite 18. Storage of signals in a memory medium located within the ECG acquiring unit or in a separate computer would not be beyond one of ordinary skill in the art.

In regard to claims 51 and 64, the signal sensed at a time instant by sensors placed on a patient's chest is plotted can be plotted on a display 16, p 16 lines 21-24 and p 18 lines 3-13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35-37, 44-48, 53-55, 58, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacAdam et al. (WO 02/058550) in view of Toole (US PG-Pub. 2002/0082510).

In regard to claims 35, 37, 53, 55, and 66, MacAdam et al. substantially describe the invention as claimed except for the focusing the cardiac analysis on the PQ-segment. Toole describes a method for analysis of the electrocardiogram and teaches

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that any segment of the ECG can be analyzed including the P, PQ, QRS, or ST-T segments, p 5 claim 7. Therefore, in view of this teaching it would be obvious.

In regard to claims 36, 40, 54, and 58, MacAdam et al. substantially describe the invention as claimed except for representing the ECG signal as a vectorcardiogram.

Groenewegen et al. does teach that early investigations of the ECG morphology have included vectors, p 2 lines 6-7. Toole teaches that another known method of ECG analysis, called vectorcardiogram, involves utilizing 3 leads, X, Y, and Z, to represent coordinate planes of the patients chest and to identify where the lead voltage are located. Therefore it would be obvious to use vectorcardiogram techniques since Toole teaches that the vectorcardiogram is useful in diagnosing abnormalities of the heart, para [0004].

In regard to claims 44-48, MacAdam et al. substantially describe the invention as claimed except for the parameters associated with the p wave. Groenewegen et al. do teach that the p wave data is classified into maps based on certain characteristics of the P waves and can be ascertained by pattern recognition algorithms, neural networks, statistical routines, etc, p 13 lines 3-15. Toole et al. performs electrocardiogram analysis by means of vectorcardiography. Though Toole does not expressly state the claimed parameters, Toole does make calculations to verify cardiac abnormalities that involve vector orientation that include calculations of angles, magnitudes, etc. The Examiner contends that one of ordinary skill in art, particularly vector algebra and calculus, at the time the invention was made would be able to determine any of the

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various parameters and make insights into their meaning associated with cardiac abnormalities.

Response to Arguments

Applicant's arguments, see Remarks, filed 1 June 2007, with respect to the rejection(s) of claim(s) 34-66 under Groenewegen et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of MacAdam et al. (WO 02/058550).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

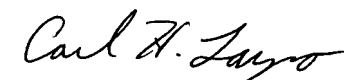
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PRIMARY EXAMINER